

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LEVINE et al.

Serial No. 10/536,800

Filed: May 27, 2005

For: SOLID MUCOADHESIVE COMPOSITION

Atty. Ref.: 4110-42

TC/A.U.: 1655

Examiner: C. Chen

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

August 5, 2007

Sir:

DECLARATION UNDER 37 CFR § 1.132

We, the inventors in the above-identified application, do hereby declare:

1. Avraham J. Domb and Joseph Simcha Wolnerman are the named inventors of U.S. App. No. 10/083,413, entitled "Absorbable Solid compositions for Topical Treatment of Oral Mucosal Disorders." This application was published on January 2, 2003, as U.S. App. Pub. No. 2003/0003140. Hereinafter, this application is referred to as "Domb" or "the Domb publication."
2. Avraham J. Domb was a paid consultant for Herbal Synthesis Corp. ("Herbal Synthesis").
3. Herbal Synthesis Corp. became Izun Pharmaceuticals Corp. ("Izun") on January 21, 2005.

LEVINE et al
Serial No. 10/536,800

4. Mr. Domb signed and executed a confidentiality agreement concerning the scope of his work for Herbal Synthesis. This confidentiality agreement is attached as Exhibit A.

5. The data that belongs to Herbal Synthesis/Izun appears in the Domb publication as Table 1, in Example 2 (pages 8-10), which, *inter alia*, discloses combinations of *Echinacea purpurea*, Elder (*Sambucus nigra*), Gotu-kola (*Centella asiatica*) and povidone (polyvinylpyrrolidone). A contemporaneously generated report reviewing the source of the data appearing in the Domb publication is attached as Exhibit B.

6. We conceived and invented subject matter appearing in the published application as noted above in paragraph 5.

7. We declare further that all statements made herein of my/our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 6th August 2007



William Levine

Date: 6th August 2007



Aron Soffer

Jerusalem Perio Center
Dr. William Levine
Dr. Aron Saffer
Periodontics • Implantology

מרכז פריו ירושלים
ד"ר זאב ליון
ד"ר אהרון סאפר
פריו • אימפלנטולוגיה

NON-DISCLOSURE AND ASSIGNMENT AGREEMENT

This Non-Disclosure and Assignment Agreement ("**Agreement**") is entered into as of the date set forth below, by and between William Levine and Aron Saffer (jointly, "**L&S**") and A. Saffer ("**Consultant**"). Consultant has been retained, for good and valuable consideration, to provide professional services in connection with the development of natural health care products (the foregoing assignment(s) referred to hereinafter as the "**Project**").

1. Disclosure of Confidential Information. L&S has disclosed or may disclose to Consultant information relating to the Project, or other information, data, technology, designs, plans, processes, systems or know-how, whether or not protected by laws affording protection for intellectual property rights, regarding L&S's natural health care products technology, or regarding current or future products based upon or related to natural health care products technology, and various business information, strategies, marketing information and customer information relating to the Project and the business of which the Project is a part (all such information disclosed by L&S to Consultant referred to hereinafter as "**Confidential Information**").

2. Confidentiality. Consultant agrees to maintain in confidence all Confidential Information and not to disclose any Confidential Information to any person. Consultant shall use Confidential Information solely to perform the Project and for no other purpose. All Confidential Information in any form, and any embodiment thereof created by Consultant in any form, are and shall be the property of L&S, and shall be delivered to L&S upon L&S's request.

3. Assignment, Consent and Delivery. All right, title and interest in and to any work (yetzirah in Hebrew) of any kind, invention, development, notes, trade, service or other mark, logo, innovation, know-how, trade secret, formula, process, computer program, code or documentation of any sort, illustration, drawing, specification, data and generally anything developed by Consultant in the course of, as part of, or in connection with the Project, including prior to the date hereof (all of the foregoing collectively, the "**Works**"), shall belong to L&S exclusively and shall be deemed "Confidential Information." To eliminate doubt, Consultant does hereby assign to L&S all such right, title and interest, and shall execute and deliver to L&S all assignments and other documents as L&S may request, to transfer and perfect all such right, title and interest. Consultant further irrevocably consents to any use that L&S may make of the Works at any time, with or without attribution. All copies of all Works shall be delivered to L&S upon L&S's request.

Dated as of 10.2, 2000.

IN WITNESS WHEREOF, the parties have duly signed this Agreement.


William Levine


Aron Saffer


Consultant

DRAFT -- September 24, 2000

HERBAL SYNTHESIS, INC.

Thursday 05 October 2000

Dear Professor Avi Domb:

We greatly appreciate all of your helpful and learned assistance to Herbal Synthesis, Inc. ("Herbal"). Enclosed please find a check in the amount of \$2,000 as full payment for all of your services through ~~add date~~ Oct. 26, 2000 *used*

A.D.

For the sake of good order we wish to clarify our understanding with you. You understand that you are required to keep all confidential non-public information regarding the Herbal Group and the projects you worked on in strict confidence and are not to make any use or disclosure of such information without our prior written consent. In addition, all inventions/discoveries made by you, if any, in the course of your consulting for the Company, Dr. William Levine, Dr. William Safer or the Perio Center Ltd. (collectively, the "Group"), are the sole property of Herbal and you will provide us with reasonable assistance in registering, filing and perfecting our ownership of any such inventions/discoveries as may be required from time to time. Obviously, we will pay your reasonable compensation for your expenses in providing such assistance.

Regarding future consulting and advice to the Group, we will contact you to discuss the nature and scope of requested services, and mutually agreeable terms for providing such assistance. However, we agree to use at least \$250 per calendar month of your services. Such fee is based upon an hourly rate for your services of NIS 100 per hour (inclusive of VAT).

We wish to clarify that our agreement is solely with you and any and all payments or expenses to any third parties in the course of your carrying out such services (including to Yissum Research and Development Company of the Hebrew University of Jerusalem ("Yissum")) shall be borne by you. The Group has not had, and shall not be deemed to have, any relationship or agreement with Yissum. Neither you, nor any third party (including Yissum) shall have any claim against the Group, other than for any unpaid consulting fees which may be owed to you from time to time.

Obviously, you are free to decline any proposed project (in which case our monthly payment shall be reduced to reflect services actually performed). Additionally, either party may terminate this agreement upon 14 days prior written notice.

We look forward to working with you in the future. Kindly sign this letter below to signify your acknowledgement of receipt of the check and agreement with the above.

Sincerely,

Herbal Synthesis, Inc.

By: 

Acknowledged and Agreed to:

Abraham S. Domb

Professor Avi Domb

Date: October 27, 2000



**Exhibit B: Report Re: Data belonging to "Herbal Synthesis"/"Izun" and
appearing in U.S. Application No. 2003/0003140 ("Domb")**

- 1 Example 2 in U.S. Application No. 2003/0003140 by Domb and Wolnerman (page 8) contains a Table (Table 1), which has 5 columns. The first column is entitled "Tablet Index" (the name given to a specific tablet composition), and the third column is entitled "Active Ingredients" and lists the active ingredients of which each tablet is comprised. This table lists 16 different compositions. As detailed hereinbelow, a large number of the samples given in Table 1 are a clear copy of the samples prepared during a project conducted for "Herbal Synthesis", and are in fact samples that Prof. Domb has been requested to check on behalf of "Herbal Synthesis".
- 2 Thus, for example, Table 1 is an almost identical copy of a report issued to "Herbal Synthesis" by Prof. Domb, through Dr. Zvilochovsky, as early as November 2000. It should be noted that Table 1 even included typographical errors appearing in the original table (for example, "bendocaine" erroneously appears in both tables as "benzocaine").
- 3 Some particular Examples of copied data are:
 - 3.1 Sample AD-2-B: Sample AD-2-B in Table 1 (AD probably stands for "Avi Domb") contains: Echinacea, Elder and Gotu-kola.
 - However, as early as July 3, 2000 (when Prof. Domb was still advising to "Herbal Synthesis"), Prof. Domb sent a letter to "Herbal Synthesis" referring to a tablet containing Gotu-kola, Echinacea and Elder (the same composition of sample AD-2-B), and further referred to it as AD-2-B, the very same name given by him to the sample later appearing in Table 1.
 - Furthermore, on July 18, 2000, Prof. Domb wrote to Prof. Katz of the Hebrew University's school of Medicine, adding a copy to Dr. Levine. At the bottom of said letter, there is a hand-written addition detailing the composition of 4 tablets. One of these (the third composition, which is named therein "collagenase I") has the same three active ingredients listed above.
 - On September 10, 2000, a lab report was issued from Prof. Domb's laboratory to Dr. Levine, containing two tables detailing compositions of tablets prepared in Prof. Domb's laboratory during the project. The second table appearing in this report describes a composition that has the same three ingredients: Gotu-kola, Echinacea and Elder. Yet further, the tested sample appearing in said report has the same quantities of the active

Ingredients, as later appearing in Prof. Domb's patent application: 1.5 ml Echinacea, 35 ml Elder and 6 ml Gotu-kola. Still further, both this report and the Domb patent application contain a remark that 2 grams of sugar were added to the tablet.

- 3.2 Sample AD-6-B, AV-20-e and AV-20-g: Samples AD-6-B, AV-20-e and AV-20-g in Table 1 contain: Echinacea, Elder and Gotu-kola. Thus, these are exactly the same active ingredients which Prof. Domb tested for "Herbal Synthesis", while acting as consultant thereof.
- 3.3 Sample AD-8-C: Sample AD-8-C in Table 1 contains: Echinacea and Gotu-kola, to which Grape extract and sugar are later added. However, in Prof. Domb's letter to Prof. Katz, dated July 18, 2000 and detailed under section 3.1 above, the fourth composition, named therein "collagenase II" has the exact same composition as later appearing in the Domb patent application.
- 3.4 Sample AV-19-g: Sample AV-19-g in Table 1 (AV probably stands for "Anti Viral") contains: Echinacea, Elder, Myrrh, Hypericum, Uncaria, and sugar. In a hand-written note from Prof. Domb to Dr. Zvilochovsky, dated from August or September, 2000, he also referred to an "Anti Viral" composition having the same active ingredients.
- 3.5 Copies of the documents listed hereinabove can be translated from Hebrew and supplied upon demand.

Date: 6th August 2007

Name: DR. WILLIAM Position: C.E.O.
LOWINE

Date: 6th August 2007

Name: DR. ARON J. Position: SENIOR VP.
GAFFER R+D.

x